REMARKS

I. PROSECUTION HISTORY

In a final action mailed August 12, 2004, the Office rejected claims 42-46 and 50-54 on various grounds including § 112, first paragraph. During telephonic interviews on July 22 & 26, 2004 and in subsequent communications, the Office indicated that those claims not rejected were allowable. Upon entrance of the present amendment, claims 26, 30, 31, and 38, 39, and 42-54 will be pending, and Applicants submit that all of these claims are in condition for allowance for the reasons presented below and as previously presented.

II. EXPLANATION OF AMENDMENTS

The amendment to the specification updates the priority claim paragraph in view of the issuance of two of the priority applications. This paragraph was previously amended as part of a preliminary amendment filed March 22, 2000 and in an amendment filed May 13, 2004. The claims are not being amended with this response. However, the claims are provided above for the convenience of the Office.

III. NEITHER THE CLAIMS NOR THE SPECIFICATION CONTAIN "NEW MATTER"

Claims 52-54 were objected to under 35 U.S.C. § 132 and rejected under 35 U.S.C. § 112, first paragraph, for allegedly introducing new matter. Applicants respectfully traverse.

Claims 52-54 are fully supported by the specification as filed. The Examiner has objected to and rejected the claims for allegedly introducing new matter, but has provided no reason why a person skilled in the art would not recognize in Applicant's disclosure a description of the invention of the invention defined by the claims. Accordingly, the Examiner has failed carry her burden in establishing a *prima facie* case. M.P.E.P. § 2163.04. Applicants, in their previous response (see page 8 of their May 2004 response), indicated specific support for claim 52-54. In that response, Applicants began by stating that the amendment introduced no new matter, found support throughout the specification, and then proceeded to provide page and line specific support for these claims: "New claim 52 finds support, *e.g.*, at page 105, line 28, to page 106, line 7. New claims 48, 50, and 53 find support, *e.g.*, at page 6, lines 25-29, page 83, lines 7-17, and page 86, lines 16-21. New claims 49, 51, and 54 find support, *e.g.*, at page 14, lines 15-18, page 25, lines 27-29."

Review of the specification reveals that Applicants contemplated use of both MDC antagonists and TARC antagonists in palliating an allergic reaction. For example, on top of page 106 (a passage pointed out by Applicant in their previous response), the specification sets out that "**agents**" that interfere with interactions of TARC or MDC with eosinophils have therapeutic indications of reducing allergic inflammatory responses. That interfering "agents" may be used indicates that both a TARC antagonist and a MDC antagonist could be used, alone or in combination, in palliating an allergic reaction. Use of humanized antibodies is supported by PCT claim 38 (of the substitute sheets; claim 31 of the amended sheets as filed in the U.S.) as well as in the specification, *e.g.*, page 82, lines 15-17. The specification identifies both anti-MDC antibodies and anti-TARC antibodies as antagonists. *See, e.g.*, at page 17, lines 16-25, page 24, lines 14-23, and page 25, lines 22-29.

Accordingly, both the new matter objection and rejection are improper and should be withdrawn. If the Office wishes to maintain the rejection, finality should be withdrawn to allow Applicants an opportunity to file a rebuttal. An objection under § 132 in any event is improper as such objection would arise only if Applicants attempted to add new matter to the specification, abstract or drawings, *see* M.P.E.P. § 2163.06.

IV. THE CLAIMS ARE ENABLED BY THE SPECIFICATION AS FILED

In paragraph 4 of the Office action, claims 42-46 and 50-51 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement. Applicants respectfully traverse and submit that no undue experimentation would be required to practice the claimed invention.

The claims are directed to the use of MDC antagonists and/or TARC antagonists that comprise antibody substances, *e.g.*, antibodies and polypeptides comprising antigen-binding fragments of the same. Applicants have presented arguments that resulted in the allowability of those claims directed to use of MDC antagonists in palliating allergic reactions. Those arguments also apply to use of TARC antagonists in palliating allergic reactions. Moreover, in Applicants' April interview with the Examiner and her Supervisor (James Housel), the Office indicated that the claims would be allowable in respect to antibodies and polypeptides comprising antigen-binding fragments of the same. For those reasons alone, the claims are enabled and the rejection should be withdrawn.

Applicants remind the Office that the claims do not require that the antibody substances have any direct or indirect interaction with CCR4 in the palliation of allergic

reactions.[1] Accordingly, earlier speculation that CCR4 may play a role in such therapies and subsequent research suggesting that CCR4 is not so involved do not detract in any way from the enabling disclosure of the specification as filed. The Conrey article cited by the Office and the Office's arguments made regarding the same are irrelevant for the same reasons.

In paragraph 7, the Office alleged that Applicants did not teach that a TARC antagonist is able to inhibit an allergic reaction *in vivo*. In their June 2003 response to the first Office action, Applicants provided as evidence of their enabling disclosure three journal articles reporting successful palliation of allergic reactions with either MDC antagonists or TARC antagonists using techniques consistent with the protocols provided in the specification. Those three journal articles were provided as Exhibits C, D, and E, and Applicants respectfully request that the Office reference those exhibits while considering the following remarks. Those articles were again discussed in Applicants May 2004 response. If the Office has allowed those claims directed to use of MDC antagonists to palliate an allergic reaction, this same evidence supports immediate allowance of those claims directed to use of TARC antagonists or such antagonists in combination with MDC antagonists. Applicants here repeat their discussion of Kawasaki, one of the previously presented articles:

Kawasaki, *et al.*, *Intervention of Thymus and Activation-Regulated Chemokine Attenuates the Development of Allergic Airway Inflammation and Hyperresponseiveness in Mice*, J. Immunol., 166: 2055-2062 (2001) (hereinafter Kawasaki) discloses an experimental study involving a mouse allergy model, in which anti-TARC antibodies are used to cause a dramatic decrease in the number of eosinophils. Kawasaki describes the methods used for the study including the use of ovalbumin as the allergen, and application of antibody prior to induction with the allergen (page 2056, column 1), which mirror the methods presented in Example 33. Kawasaki states: "Treatment with anti-TARC Ab strikingly decreased the total cell number and the number of eosinophils as well as lymphocytes recovered in the lavage fluid compared with those in the group treated with control Ab (Fig. 4)." (Page 2058 and in figure 4 on page 2059.) A decrease in neutrophils is also reported (*see* figure 4) in agreement with Example 33 (specification, page 108, lines 1-2). Accordingly, Kawasaki demonstrates that the invention using TARC antagonists can be practiced effectively to palliate an allergic reaction, *i.e.*, *in vivo*, as disclosed in the present application.

[1] However, the lack of such a requirement does not exclude CCR4 from playing a role in palliation.

In paragraph 7, the Office also alleged that "the specification lacks teaching and does not provide any guidance related to how the TARC antagonist is generated." The Office also discussed alleged lack of TARC antibody teachings in paragraphs 11 through 17. Applicants respectfully traverse because the specification clearly sets out how TARC antagonists can be made. *See* page 83, lines 8-14. TARC nucleic acid and amino acid sequence is taught in the specification (SEQ ID NOS: 42 and 43, *see also* at page 83, lines 8-14) and consequently one of skill in the art would understand how to generate anti-TARC antibody substances just as they would understand from the teachings in the specification and the knowledge available in the art how to generate anti-MDC antibody substances. Antibody production (both monoclonal and polyclonal) is described in detail in Example 18, pages 69-78. Applicants need not have actually produced a TARC antibody to enable the claims; teaching how to make such antibody or such teaching already present in the art is sufficient. The procedures described work as they successfully produced MDC antibodies and would be expected by a person of skill in the art to work for TARC as well as other antigens.

In paragraph 8, the Office alleged that the "scope of the claims read broad with a method for treating allergic reaction by using any or all TARC antagonists." However, brief inspection of the claims directed to TARC antagonists, *e.g.*, claim 42, shows that the claims are directed to TARC antagonists comprising an **antibody substance** that specifically binds to a vertebrate TARC polypeptide. The Office is not permitted to read limitations into the claim and is also not permitted to ignore claim limitations when examining the claims.

In paragraph 9, the Office characterized the level of skill in the art as "high." The greater the knowledge in the art about the field of the invention, the less information needs to be explicitly stated in the specification. *See* M.P.E.P. § 2164.03. The specification of the present application provides detailed guidance regarding antagonists, *see, e.g.*, pages 24-26 and 82 of the specification, and to methods of using an antagonist to palliate an allergic reaction in a mammalian host, *see, e.g.*, Example 33. The detailed instructions in the specification, combined with the high level of skill in the art, means that the specification is enabling. Moreover, *in vitro* experiments can be extrapolated to *in vivo* efficacy, *see, e.g.*, discussion of the specification and Kawasaki above.

In paragraphs 11-17, the Office rejected claims 44 and 45 under 35 U.S.C. § 112, first paragraph, and alleged that a TARC monoclonal antibody was an essential element for the claimed method. The Office then proceeded to request deposit information

for TARC monoclonal antibodies. As discussed above, Applicants have sufficiently enabled one of skill in the art to produce antibodies (polyclonal and monoclonal) against both MDC and TARC. Applicants believe they properly complied with Office regulations for the anti-MDC monoclonal antibodies produced and the hybridomas that produced those antibodies (see specification at page 72). Because particular, specific anti-TARC antibodies and hybridomas producing the same were not identified in the specification, there is no deposit information to provide. Again, Applicants are not required to have actually produced antibodies against MDC or TARC in order to meet the patentability requirements for claiming such antibodies or methods utilizing the same.

Accordingly, the rejection of the claims under 35 U.S.C. § 112, first paragraph, should be withdrawn.

CONCLUSION

Applicants respectfully request prompt reconsideration of the pending claims and withdrawal of the objections and rejections. The claims are believed to be in condition for allowance in view of the foregoing amendments and remarks. Accordingly, Applicants respectfully request notice of allowance of all claims pending.

The Examiner is invited to contact the undersigned at the telephone number listed below in order to discuss any remaining issues or matters of form that will move this case to allowance.

Respectfully submitted,

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